

BEFORE THE IOWA BOARD OF PHARMACY

RE:
Limited Use Pharmacy License of

HY-VEE PHARMACY 3191
License No. 1628
Respondent.

CASE NO. 2018-93

**NOTICE OF HEARING AND
STATEMENT OF CHARGES**

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Hy-Vee Pharmacy 3191 ("Respondent"), 1224 10th Ave N, PO Box 895, Manson IA 50563, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.6 and 35.7. Respondent's Iowa limited use pharmacy license number 1628 is currently active through December 31, 2019.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on March 12, 2019, before the Board. The hearing shall begin at 1:00 p.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 SW 8th St, Ste E, Des Moines IA 50309.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.16. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

Filing of Pleadings. Pleadings shall be filed with the Board either by e-mail, if done in compliance with 657 IAC 35.17(2), to Amanda.Woltz@iowa.gov, or by mail/delivery to the following address: Iowa Board of Pharmacy, 400 SW 8th St, Ste E, Des Moines IA 50309.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the Board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the contested case hearing, including prehearing matters, are found at 657 IAC chapter 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. The hearing may be open to the public or closed to the public at your discretion, pursuant to Iowa Code section 272C.6(1) and 657 IAC 35.25(10).

Prosecution. The Office of Attorney General of Iowa is responsible for representing the public interest (the State) in this proceeding. Counsel for the State in this matter is Assistant Attorney General Laura Steffensmeier. Ms. Steffensmeier can be reached by phone at (515) 281-6690. Copies of pleadings should be provided to counsel for the State either by email to Laura.Steffensmeier@ag.iowa.gov, or by mail/delivery to the following address:

Laura Steffensmeier
Assistant Attorney General
Hoover State Office Building—2nd Floor
1305 E Walnut St
Des Moines IA 50319

Communications. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file and serve upon all parties in the case.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 155A, and 272C (2018).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 155A and 272C, and 657 IAC chapter 36. Pursuant to 657 IAC 8.3(2) and 13.4, the pharmacy, by and through its owner or license holder, shall work cooperative with the pharmacist in charge and with all staff pharmacists to ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 IAC 35.27.

C. STATEMENT OF CHARGES

COUNT I

FAILING TO MAINTAIN ELECTRONIC ENTRY SYSTEM

Respondent is charged with failing to maintain an electronic entry system into the telepharmacy as required by 657 IAC 13.8(3)"a", and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT II

FAILING TO DISPLAY REQUIRED SIGNAGE

Respondent is charged with failing to display the required telepharmacy site signage at every prescription pick-up area in violation of 657 IAC 13.8(4) and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT III

TECHNICIAN WORKING WITHOUT PROPER IDENTIFICATION

Respondent is charged with having a telepharmacy technician work without wearing a name badge or tag identifying the technician in violation of 657 IAC 13.11(4), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT IV

FAILING TO COMPLY WITH MONTHLY INSPECTION REQUIREMENTS

Respondent is charged with failing to maintain monthly inspection reports as mandated by 657 IAC 13.9(5) and 13.23(4), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT V

FAILING TO ESTABLISH AND MAINTAIN EFFECTIVE CONTROLS

Respondent is charged with failing to establish and maintain effective controls against the theft or diversion of prescription drugs, including controlled substances, and records for such drugs as required by 657 IAC 8.3(5)"b", and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT VI

TECHNOLOGY FAILURE

Respondent is charged with failing to comply with 657 IAC 13.8(9), which prohibits a telepharmacy site from dispensing prescriptions to patients if the audiovisual technology between the telepharmacy site and the managing pharmacy or verifying pharmacist is not operational, and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

D. FACTUAL CIRCUMSTANCES

1. Respondent began operating as a telepharmacy site in Manson in November 2017. Respondent is managed by Hy-Vee Pharmacy 1192.

2. On July 25, 2018, Respondent underwent a routine inspection which revealed the following deficiencies:

- a. Respondent was not maintaining electronic entry system records.
- b. The required telepharmacy site signage was not displayed at Respondent's drive-thru window.

- c. The technician on duty was not wearing a name tag.
 - d. Respondent did not have records for the required monthly inspections for November 2017, December 2017, and January 2018.
3. A subsequent audit of Respondent's records revealed a shortage of tramadol tablets.
4. Respondent provided the Board with a scanned image of a prescription that was utilized by the pharmacist to verify a prescription. The scanned image was of poor quality, which suggested the equipment was not able to provide a high enough quality image to allow the verifying pharmacist to compare the electronic image of the prescription with the data entry record of the prescription.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 35.24. To cancel a scheduled hearing, an executed settlement agreement must be received by the Board at least three (3) business days prior to the scheduled hearing. If you are interested in pursuing settlement in this matter, please contact the Assistant Attorney General identified above.

F. FINDING OF PROBABLE CAUSE

On January 9, 2019, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Hoover State Office Building—2nd Floor
1305 E Walnut St
Des Moines, IA 50319
ATTORNEY FOR THE STATE

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).